Inventor: El-Raghy and Barsoum

Serial No.: 10/666,639

Filing Date: September 19, 2003

Page 4

#### REMARKS

Claims 1-3 are pending in the instant application. Claims 1 through 3 have been amended. Support for these amendments is provided at page 4, lines 13-16 and page 6, lines 17 through 24. No new matter is added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Amendment to Claim 1

The Examiner suggests that evidence in the Declaration submitted by Applicants is suggestive of prior conception and some reduction to practice of the invention as currently claimed because no particular former structure or method of making the former is claimed. Accordingly in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to state that the former structure is comprised of more than 50%  $M_{n+1}AX_n$ . Support for the amendment is provided in the specification at page 4, lines 13-16. In contrast, portions of Exhibit A set forth at page 3 of the instant Office Action reference a ceramic condom former merely coated with  $Ti_3SiC_2$ . This amendment, clearly supported by teachings of the specification, sets forth the structure of the instant claimed former and clearly distinguishes the present invention from

Inventor: El-Raghy and Barsoum

Serial No.: 10/666,639

Filing Date: September 19, 2003

Page 5

alternative research efforts described in Exhibit A of the Declaration. Entry of this amendment and withdrawal of issues relating to Dr. Knights' participation in conception and/or reduction to practice of the instant claimed invention is therefore respectfully requested.

#### II. Response to Request for Information

The Examiner has requested additional information relating to an e-mail of February 22, 2000 which refers to a payment check to Drexel. Specifically, the Examiner is concerned about the nature of this transaction and the potential public use or on sale statutory bar under 35 U.S.C. 102(b). This February 22, 2000 e-mail is responsive to an e-mail sent by inventor El-Raghy on Friday September 3, 1999 and relates only to re-imbursement of costs to Drexel University for raw materials, processing and machining of a solid condom former. A copy of this September 3, 1999 e-mail is provided herewith as Attachment A. preliminary e-mails between Stanley Gromelski and Dr. Tamer El-Raghy resulted in a Sponsored Research Agreement between Ansell Healthcare Products of which Stanley Gromelski was an employee and Drexel University. A copy of this Sponsored Research Agreement is provided herewith as Attachment B. Clear from this Sponsored Research Agreement entered into in June of 2000 is that

Inventor: El-Raghy and Barsoum

Serial No.: 10/666,639

Filing Date: September 19, 2003

Page 6

in no way were the glove and condom formers of the instant invention complete and/or ready for patenting as of the September 1999 or March 2000 emails as required at the time of sale to invoke the "on sale" bar (see MPEP 2133.03(c)). Also clear from the Sponsored Research Agreement is that the primary purpose of these preliminary e-mails and exchange of goods was to conduct experimentation to perfect claimed features and/or characteristics and thus constitutes a permitted activity. See MPEP 2133.03(e). Applicants believe the provided evidence should overcome any concerns of the Examiner regarding this issue under 35 U.S.C. 102(b).

Withdrawal of this rejection is therefore respectfully requested.

# III. Rejection of Claims 1-3 under 35 U.S.C. 102(e) and 35 U.S.C. 103

Claims 1 and 2 have been rejected under 35 U.S.C. 102(e) as being anticipated by Gromelski (WO 03/051791). Claim 3 has also been rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative under 35 U.S.C. 103(a) as obvious over Gromelski in view of Applicants admitted prior art (pages 1-2 of the Written Description).

Applicants respectfully traverse these rejections.

DRE-0111

Inventor:

El-Raghy and Barsoum

Serial No.:

10/666,639

Filing Date:

September 19, 2003

Page 7

The Declaration submitted by Applicants with the prior response was suggested by the Examiner to raise other questions concerning prior conception and reduction to practice. As discussed in Section I, however, prior work related to a coated ceramic former, not a former comprising more than 50%  $M_{n+1}AX_n$  as now claimed. Reconsideration of the Declaration in light of this claim amendment is therefore respectfully requested.

Further, as discussed in Section II, Applicants are submitting herewith a copy of the Sponsored Research Agreement between Ansell Healthcare Products and Drexel University wherein it is made clear that these groups were working together to develop slip casted glove and condom mandrels as set forth in Gromelski et al.

This sponsored research agreement provides additional evidence that WO 03/051791 is not the work of another and therefore is not a valid prior art reference under 35 U.S.C. 102(e) or 35 U.S.C. 103.

Withdrawal of these rejections under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) is therefore respectfully requested.

#### IV. Rejection of Claims 1-3 under 35 U.S.C. 103(a)

Claims 1 and 2 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Adasch et al. (U.S. Patent 5,194,204) in

DRE-0111

Inventor:

El-Raghy and Barsoum

Serial No.:

10/666,639

Filing Date:

September 19, 2003

Page 8

view of Barsoum et al.(J. Am. Ceram. Soc. 79[7] (1996) 1953-56). Claim 3 has also been rejected as being unpatentable over Adasch et al. in view of Barsoum et al. and further in view of Hadfield (U.S. Patent 1,635,576).

Applicants respectfully traverse these rejections.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that teachings of Barsoum et al. are "not directed to a metal".

Teachings of Barsoum et al. relate to synthesis and characterization of Ti3SiC2. Ti or titanium is a metal.

Further, as taught in the instant patent application as well as by Barsoum et al. at page 1956, Ti3SiC2 has properties of both metals and ceramics (see teachings in specification at page 5, lines 21-30 as well as page 1956 of Barsoum et al. wherein it is stated that "Ti3SiC2 is a remarkable material in that it combines many of the best attributes of both metals and ceramics.")

Accordingly, one of skill would not be motivated to substitute the material of Barsoum et al. with its metal properties into the process of Adasch et al. when prior art teachings such as Adasch et al. teach that metal formers corrode rapidly (see Adasch et al. at col. 1, lines 9-16) and are more liable to scratch (see Adasch et al. at col. 1, lines 17-19).

DRE-0111

Inventor:

El-Raghy and Barsoum

Serial No.:

10/666,639

Filing Date:

September 19, 2003

Page 9

Further Adasch et al. teaches that an advantage of using the silicized silicon carbide is that the density of 2.8 to 3.1 g/cm<sup>3</sup> is in the range of aluminum alloys and thus results in dipping formers only slightly heavier than those made of porcelain or aluminum (see col. 1, lines 49-53). In contrast, Barsoum et al. teaches the density of Ti3SiC2 to be 4.53 g/cm<sup>3</sup>, approximately 1.5 fold higher than the materials disclosed for use in the formers of Adasch et al. Accordingly, one of skill would have no motivation to substitute this heavier metal containing compound taught by Barsoum et al. into the process of Adasch et al.

Further, one of skill in the art would have no reasonable expectation of success that the material of Barsoum et al., explicitly taught at page 1956 to exhibit attributes of both metals and ceramics, would be useful in producing a former resistant to corrosion by acids and alkalis, particularly since the cited art teaches aluminum and steel formers to corrode. (See Adasch et al. and Gromelski et al.)

In an earnest effort to advance the prosecution of this case, Applicants have amended the claims in accordance with teachings at page 6, lines 17 through 24 to state that the former is resistant to corrosion by acids and alkalis. This claim limitation is not taught or suggested by the cited prior art.

Inventor: El-Raghy and Barsoum

Serial No.: 10/666,639

Filing Date: September 19, 2003

Page 10

Thus, since the combination of Adasch et al. and Barsoum et al. fail to provide the requisite motivation to combine their teachings, the reasonable expectation of success with respect to the instant claimed invention, and a teaching or suggestion of all the limitations of the instant claims, this combination of references cannot render obvious claims 1 and 2. See MPEP 2143.

Further with respect to claim 3, MPEP 2143.03 is clear; if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. Also see In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claim 3 is dependent from claim 1. As discussed in detail in the preceding paragraphs, the combination of Adasch et al. and Barsoum et al. do not render obvious claim 1. The secondary reference of Hadfield (U.S. Patent 1,635,576) fails to remedy the deficiencies in the teachings of Adasch et al. and/or Barsoum et al. as this reference provides methods for producing a glove or condom using a standard former, not a glove or condom former resistant to corrosion by acids and alkalis comprising more than 50%  $M_{n+1}AX_n$  as claimed. Accordingly, the combination of Adasch et al., Barsoum et al. and Hadfield cannot render obvious dependent claim 3.

DRE-0111

Inventor:

El-Raghy and Barsoum

Serial No.:

10/666,639

Filing Date:

September 19, 2003

Page 11

Withdrawal of these rejections under 35 U.S.C. 103 is therefore respectfully requested.

#### III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A.

Registration No. 38,350

Date: October 17, 2005

Licata & Tyrrell P.C. 66 E. Main Street

Marlton, New Jersey 08053

(856) 810-1515

## **Attachment A**

Date: Fri, 3 Sep 1999 10:25:09 -0500

To: sgromels@ansell.com.au

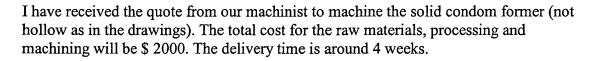
From: Tamer El-Raghy <sg94d216 Subject: Re: Ti3SiC2 Bulk samples

Cc: barsoum

Bcc:

X-Attachments:





OCT 1 7 2005

If you have any questions, please feel free to contact me. I look forward to receiving your reply.

Sincerely,

Tamer

# **Attachment B**





## SPONSORED RESEARCH AGREEMENT

between

# ANSELL HEALTHCARE PRODUCTS Incorporated (SPONSOR)

and

DREXEL UNIVERSITY

## SPONSORED RESEARCH AGREEMENT

This Sponsored Research Agreement ("Agreement") is made by and between Drexel University, a Pennsylvania nonprofit corporation ("DREXEL"), with offices located at 32nd & Chestnut Streets, Philadelphia, PA 19104 and Ansell Healthcare Products Inc. ("AHP"), a corporation having a place of business at 1875 Harsh Ave SE, Massillon, Ohio 44646.

This Agreement is effective as of the 20th day of June, 2000. ("EFFECTIVE DATE").

## Section 1 - Definitions.

- (a) "AHP" means Ansell Healthcare Products Inc.
- (b) "University" means the university, college, institute, or the like organization identified in the addressee space on Purchase Order defined in (d) below.
- (c) "Contract Services" means the services to be rendered by University as specified in Purchase Order to develop applications for Ti<sub>3</sub>SiC<sub>2</sub> and related materials.
- (d) "Purchase Order" means the AHP Purchase Order addressed to University and to which this document is attached and forms a part thereof.
  - (e) "Contract" means Purchase Order and these Terms and Conditions.
- (f) "Field of Applications" means the development of ceramic slip casting and former coatings for glove and condom mandrels. It is hereby understood that other applications can in the future be added to the Field of Applications definition upon written notification from AHP. University has the right to refuse any such additional applications. All applications dealing with the casting and pouring of molten steel are not included in this agreement.
- (g) "EFFECTIVE DATE" means the date the last party to this Agreement signs in the space below.
- (h) "INTELLECTUAL PROPERTY" means all data, know-how, information, discoveries, inventions, and improvements, including computer software, in the Field of Applications and arising from the work performed under this Agreement.

## Section 2 - Facilities and Personnel.

The Contract Services shall be performed at University. University shall secure and provide personnel, laboratory facilities, equipment, material, and services including library services and supplies. If a principal investigator or any specific subordinate investigator is named in Purchase Order, such principal investigator shall approve other personnel and act as project supervisor, and such principal or other named investigator shall not be changed without AHP's permission.

## Section 3 - Reports.

Unless otherwise specified in Purchase Order, a final report shall be made to AHP by University upon completion of the Contract Services. In the interim, University or the principal investigator shall keep AHP informed of the progress of the Contract Services with written reports as warranted by the progress of the work and with oral or written reports upon AHP's reasonable request. AHP may designate portions or all of such reports as "Confidential" information under its Limited Use and Nondisclosure Agreement with University, said agreement being: (i) dated March 17, 1998; (ii) fully incorporated by reference herein; and (iii) hereinafter referred to as the "Nondisclosure Agreement".

## Section 4 - Data, Know-How, Inventions, Patents, and Copyrights.

- (a) University promptly shall disclose to AHP all data, know-how, information, discoveries, inventions, and improvements, including computer software, conceived, made, first reduced to practice, or developed by University arising in the performance of Contract Services (hereinafter "Contract Data").
- AHP and University, and may result in patentable technology in the Field of Applications, such patents resulting from University's performance of Contract Services hereunder will be jointly owned by AHP and University. For AHP to use that technology on a commercially exclusive basis, a licensing agreement will have to be negotiated in good faith between AHP and University. University and AHP will negotiate in good faith to determine the terms of a license agreement as to each item of INTELLECUTAL PROPERTY for which AHP desires a license. University agrees to grant AHP a right of first option to exclusively license INTELLECTUAL PROPERTY, in a writing clearly and completely providing the terms of the license. University agrees that the terms of the license under the right of first option will be commercially reasonable terms. The University shall be free to license its interest in the INTELLECTUAL PROPERTY to any party upon such terms as the University deems appropriate, without any further obligation to AHP, if the parties fail to execute a license agreement for the INTELLECUTAL PROPERTY within six (6) months after the termination of this Agreement.
- (c) University shall cooperate with AHP to prepare, file, and prosecute applications for and obtain patents thereon as AHP deems available and desirable in any and all countries selected by AHP, as well as continuations, continuations-in-part, reissues, renewals, and extensions thereof. Any reasonable additional costs incurred by University to support this obligation will be reimbursed by AHP.
- (d) The confidentiality obligations imposed on University under this Agreement shall continue in force until the earliest to occur of the following: (a) the relevant information enters into the public domain; and (b) a patent is obtained, as provided herein, that protects the relevant information previously subject to the confidentiality obligation.
- (e) Any license granted to AHP pursuant to Section 4(b) hereof shall be subject, if applicable, to the rights of the United States government reserved under Public Laws 96-517, 97-256 and 98-620, codified at 35 U.S.C. 200-212, and any regulations issued thereunder.

## Section 5 - University Publication.

Subject to prior approval by AHP, which approval shall not be unreasonably withheld, University may publish results of the Contract Services ("Contract Results"); provided, however, that AHP may delay any publication for up to six (6) months from the date University submits a request for publication approval to AHP; and provided further that publication of Contract Results shall be confined to general statements of results achieved, advantages obtained, or problems solved without violating any provision of the Nondisclosure Agreement, including those provisions respecting Contract Data developed by University in performing Contract Services. If portion(s) of a proposed publication would include AHP Information or Contract Data protected by the Nondisclosure Agreement, AHP shall have the right to modify or cancel said portion(s) from the proposed publication so as to protect such information. AHP shall be provided with a draft of any proposed publication clearly marked "To restrict publication, AHP must so direct within ninety (90) days". Failure by AHP to respond within ninety (90) days of receipt of such draft so marked shall constitute implied AHP permission to publish, except that no such publication may contain AHP Information protected by the Nondisclosure Agreement without the express (and not implied) written sent of AHP.

#### Section 6 - Publicity.

No advertising, announcement, publication, statement or any other publicity matter, either oral or written, having or containing any reference to the existence of this Agreement or in which the name of either party is mentioned shall be made until written approval has been obtained from the other party.

## Section 7 - Indemnification.

- (a) University agrees to hold AHP harmless and to indemnify AHP against any and all claims, including claims for injury or loss to property or life, by others including University employees, students, agents and contractors arising out of or resulting from performance by University, its employees, agents, officers or students, of Contract Services under this Agreement.
- (b) AHP agrees to hold University harmless and to indemnify University against any and all claims for injury or loss to property or life, by others including AHP employees, agents and contractors, arising out of or resulting from any use by AHP of any reports, know-how, data, inventions, or patents resulting from Contract Services under this Agreement.

## Section 8 - Independent Contractor.

(a) University's relationship to AHP in the performance of this Agreement is that of independent contractor. The personnel performing the services under this Agreement shall at all times be under University's exclusive direction and control and shall be employees or agents of University and not employees or agents of AHP. Such personnel shall not be eligible for AHP benefits or employee plans.

- (b) University shall have no authority to direct or control the performance of any employee of AHP. If instruction of AHP employees is involved, University's role shall be that of advisor and not of master. University is to advise AHP employees as to its opinion of matters covered by Contract Services, but shall not be responsible for any AHP action that may logically follow the giving of such advice.
- (c) University shall procure all licenses, permits or other approvals from Government authorities which are necessary for performance of the Contract Services for AHP.

#### Section 9 - Notice.

All notices, approvals, consents, requests or demands required or permitted to be given under this Agreement shall be in writing and shall be deemed sufficiently given when deposited in the mail, registered or certified, postage prepaid, and addressed to the party entitled to receive such notice at the address shown on Purchase Order, provided that any party may subsequently designate another address by notice given in accordance with this Section 9. If notice is given by any other method than that stated herein it shall be deemed effective only when the written notice is actually received.

## Section 10 - Skills, Performance and Conflict of Interest.

- (a) University professes to possess skills or professional ability requisite to perform Contract Services but does not guarantee success in achieving all Contract Services' goals.
- (b) University represents that it has the right to enter into this Agreement and perform the Contract Services for AHP, and that no restrictions whatsoever have been imposed on it or its employees, students or agents under any other agreement, instrument, law or rule which would prevent it from performing this research or complying with all the provisions of this Agreement.
- (c) University shall comply with the safety laws and regulations of AHP applicable at the site or facility, if any, where the Contract Services are performed.
- (d) When any Contract Services are performed upon the premises or property of AHP or when University or its agents or employees visit an AHP facility in connection with Consulting Services or disclosure of Confidential Information, such visitors during such visits shall be on the business of University and not AHP and shall comply with the safety rules and other rules of AHP which are applicable at such sites or facilities of AHP. These rules include, but are not limited to, the AHP Corporate Policy on Substance Abuse which applies to University and all students, agents, representatives, employees and invitees thereof and to AHP authorized subcontractors of University, while performing services on AHP property or work sites, as follows:
  - i. The use, sale, transfer or possession of illicit drugs or controlled substances without a doctor's prescription on AHP property or work sites is strictly prohibited.

- ii. The use, sale, transfer or possession of alcohol on any AHP property or work sites is strictly prohibited except with prior approval by an appropriate official of AHP. This prohibition and that contained in above Item i applies to University vehicles, as well as to any private vehicles on AHP property or work sites.
- iii. No person may be at work on AHP property under the influence of alcohol, drugs or controlled substances. No person will be permitted to remain at work on AHP property or work sites when their performance is affected by alcohol, drugs, or controlled substances.
- iv. Where appropriate in AHP's judgment, testing will be utilized to determine the presence of alcohol, drugs, or controlled substances.
- v. AHP reserves the right to conduct searches or inspections of any person of University and his or her personal belongings located on AHP property for cause or as part of a general inspection on as a means of enforcing the provisions of this policy. Such searches or inspection may include, for example, University employees' personal effects, lockers, desks, lunch boxes, purses, briefcases and private vehicles located on AHP property or work sites.
- vi. Any University employee on AHP property or work sites found in violation of this policy will be refused entry to, removed from and/or excluded from AHP property or premises.

Violation of this policy may result in termination of this contract as well as other consulting contracts between AHP and University.

## Section 11 - Amendments and Waiver.

- (a) This Agreement may not be amended, released, discharged, abandoned, changed, or modified in any manner except by an instrument in writing signed by a duly authorized officer or representative of each of the parties hereto.
- (b) The failure of either of the parties hereto to enforce at any time any of the provisions of this Agreement or to exercise any right which is herein provided shall in no way be construed to be a waiver of such provision nor in any way to affect the validity of this Agreement or any part thereof or the right of either party hereto to enforce thereafter each and every such provision and to exercise any such right. No waiver of any breach of this Agreement shall be held to be a

waiver of any other or subsequent breach. Nothing shall constitute, or have the effect of, a waiver except an instrument in writing signed by a duly authorized officer or representative of the party against whom such waiver is sought to be enforced which expressly, and not impliedly, waives a right or rights under this Agreement.

#### Section 12 - Termination.

AHP may for its own convenience terminate this Agreement and University's right to proceed with some or all of the Contract Services to be performed hereunder by giving written notice to University. Upon receipt of notice of termination, University shall immediately discontinue the Contract Services unless the notice states otherwise.

#### Section 13 – Purchase Orders.

AHP will provide payment for the performance of Contract Services by University by means of Purchase Order. The duration of the Contract Services shall also be provided by Purchase Order, however, AHP may terminate this Agreement and Purchase Order as provided in Section 12 of this Agreement.

## Section 14 - Miscellaneous Provisions.

- (a) University shall obtain agreements to effectuate the provisions of the Nondisclosure Agreement and Section 4 from all persons performing any part of the Contract Services hereunder except non-technical personnel, such as clerical employees.
- (b) University shall provide a copy of this Agreement to any person performing Contract Services hereunder or to the supervisor of such person.
- (c) This Agreement shall inure to the benefit of and be binding upon AHP, its successors and assigns. This Agreement shall not be assigned by University without the prior written consent of AHP, and only in the manner and to the extent specified in such consent. Nothing in this Agreement, express or implied, is intended or shall be construed to confer upon any person other than the parties hereto any right, remedy or claim under or by reason of this Agreement.
- (d) Except for the Nondisclosure Agreement, this Agreement sets forth the entire agreement and understanding between the parties as to the subject matter of this Agreement, and merges and supersedes all prior agreements, commitments, representations, writings and discussions between them, whether written or oral. It is expressly understood that no representations, promises, warranties or agreements have been made by either party except as the same are set forth herein. Except as otherwise expressly provided in this Agreement, this Agreement may not be amended or terminated except in writing and signed by the proper and duly authorized representative of the party to be bound thereby.

- (e) If any provision of this Agreement or its application to any person or circumstance is adjudged invalid or unenforceable by a court of competent Jurisdiction, then the remainder of this Agreement or the application of such provision to other persons or circumstances shall not be affected thereby; provided, however, that if any provision or application hereof is invalid or unenforceable, then a suitable and equitable provision shall be substituted therefor in order to carry out, so far as may be valid and enforceable, the intent and purpose of this Agreement including the invalid or unenforceable provision.
- (f) The captions of the Sections of this Agreement are for convenience only and shall not control or affect the meaning or construction of any of the provisions of this Agreement.
- (g) This Agreement shall be governed by and interpreted in accordance with the laws of the Commonwealth of Pennsylvania, not including, however, the rules relating to the choice or conflict of laws.
- (h) It is understood that University is subject to the laws and regulations of the United States which laws control the export of technical data, University software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended, and the Export Administration Act of 1979), and that its obligations hereunder are contingent on its compliance with all applicable export laws and regulations of the United States. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by University and/or AHP that no data or commodities shall be exported to certain foreign countries without the prior approval of such agency.
- (i) When AHP or its employees or agents visit a University facility in connection with this Agreement, such visitors during such visits shall be on the business of AHP and not of University, and shall comply with all written University rules and policies that are provided to the visitors prior to their visits.
  - (j) Notices, payments, statements, reports and other communications under this Agreement shall be in writing and shall be deemed to have been received as of the date dispatched if sent by public overnight courier (e.g., Federal Express) and addressed as follows:

#### If to DREXEL:

Vice President for Research Drexel University 3201 Arch Street, Suite 100 Philadelphia, PA 19104

### with a copy to:

Office of the General Counsel Drexel University 3141 Chestnut Street Philadelphia, PA 19104 Attn: General Counsel

## If to ANSELL HEALTHCARE PRODUCTS Inc.

Dr. Paul Cacioli Senior Vice President Science and Technology Ansell Healthcare Products Inc. 1875 Harsh Ave SE Massillon, Ohio 44646.

DREXEL UNIVERSITY

Name: Harvill Eaton

Title: VP for Research

Date: 6-12-00

ANSELL HEALTHCARE PRODUCTS Inc.

Name: Dr. Paul Cacioli

Title: Senior Vice President Science and

Technology

Date: June 20, 2000

I have read and agreed to the responsibilities of the PRINCIPAL INVESTIGATOR:

Grifos Date: